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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,607	03/26/2001	Fei Yang	DEX-0201	7851

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 08/13/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,607	FEI YANG	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,7,8 and 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5, 6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VIII (claims 1, 3-6 and 9) in Paper No. 8, received May 22, 2002 is acknowledged. The traversal is on the ground(s) that SEQ ID NO: 1-57 should be regarded as species and not separate inventions. Applicants set forth arguments based on MPEP 806.04(f). This is not found persuasive because Applicants have not set forth any evidence disclosing that all fifty-seven sequences are from the same parent sequence or that they share any base pair complementarity. Absent any evidence to the contrary each sequence is regarded as a separate invention due to the fact that each separate nucleic acid sequence encodes different products, which are materially different from one another.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-25 are pending.

Claims 2, 7, 8 and 10-25 are drawn to non-elected inventions.

Claims 1, 3-6 and 9 are examined to the extent they read on SEQ ID NO: 8, a polynucleotide.

Information Disclosure Statement

3. The information disclosure statement filed September 24, 2001, Paper No. 5 lists a number of documents that were to be considered by the Examiner. However, not all of the documents were found in the instant application available for review, particularly

references AB, AD-AF and AN-AP. Hence, the listed documents "lined through" were not reviewed during examination and not considered. The Applicant is invited to submit the references for consideration.

Claim Objections

4. Claim 1 is objected to because of the following informality: it contains reference to non-elected inventions. Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' claims encompass an isolated polynucleotide (SEQ ID NO: 8), as well as fragments and variant sequences that encode the same protein encoded by as SEQ ID NO: 8. The said claims also include a polynucleotide which comprises a nucleic acid sequence which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO: 8 contained within a vector and host cell, a method for producing said

polynucleotide, regarded as a CSG molecule and using the said molecule for diagnoses of colon cancer.

Applicants' specification does not evidence the intended use of SEQ ID NO: 8, nor fragments and variant sequences. On pages 57 and 58 the application provides Tables 4-6, which show levels of expression of sqcln017 (also known as SEQ ID NO: 8 or Clone Id clnc00000827) in numerous samples including normal samples and colon cancer samples. None of these tables exemplify the discriminate detection of colon cancer given that sqcln017 is detected in corresponding normal adjacent tissue (see Table 6) and breast and stomach carcinomas (see Table 5). The specification does not enable one of ordinary skill in the art to definitively assess the incidence of any type of cancer, particularly colon cancer. There is insufficient evidence provided to support the use of the said sequences in a diagnostic method for colon cancer. Furthermore, Applicants have not provided any disclosure enabling the use of degenerate coding sequences of SEQ ID NO: 8. There is no disclosure designating what changes to the coding sequences could be tolerated enabling one of ordinary skill in the art to make and use the said sequences in any diagnostic method. The experimental design presented in the specification lacks information regarding the applicability of SEQ ID NO: 8 and degenerate coding sequences thereof in diagnostic methods relative to colon cancer. Given the differing pathologies of cancer within different organ systems and data observed in Table 5 revealing sqcln017 expression in breast, stomach, testes and uterus and not in the colon cancer sample it is reasonable to conclude that SEQ ID NO: 8 and its degenerate coding sequences would not be effective in yielding a discriminate

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diagnosis for colon cancer. Applicants have not set forth any supporting evidence that suggests that SEQ ID NO: 8 is a unique tumor or molecular marker for colon cancer.

Based on the analysis set forth it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims.

7. Claims 1, 5, 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitation "hybridizing under stringent conditions" in claim 1 is vague and indefinite. The metes and bounds are unclear in the absence of limitation specifying specific stringency conditions.

b. The recitation "CSG" in claims 5, 6 and 9 is indefinite. The Applicants are advised to amend the claims to include the full terminology and recite "colon specific gene (CSG)".

8. Claims 1, 3-6 and 9 are free of the art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alana M. Harris, Ph.D.
August 12, 2002